

EPA REGISTRATION NUMBER 69268-2 – VOL. 2

SUBM. DUE DATE 04-05-06

REVIEWER K Leary-Maink

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

DESCRIPTOR Notification FOIPA X NFOIPA

☐ CHILD RESISTANT PACKAGING: ☐ REQUIRED ☐ NOT REQUIRED

REGISTRATION TYPE: ☐ CONDITIONAL ☐ UNCONDITIONAL ☐ RESTRICTED USE

EPA RECEIVE DATE

PM RECEIVE DATE

02128106

03/06/08

53108106

METHOD OF SUPPORT

FORMULATORS EXEMPTION

[] CITE-ALL	[] SELECTIVE
[] NOT SUBMITTED	[] N/A

[] SUBMITTED [] NOT SUBMITTED
[] E/A

REVIEW(S) REQUESTED

DATA
PACK #

DATE
SENT

**DUE
DATE**

DATE
RETURNED

CHEMISTRY _____] [_____] [_____]

EFFICACY _____

ACUTE TOX. _____] [_____] [_____] [_____]

RASSB TOX. _____] [_____] [_____] [_____]

ENVIRON. PATB _____] [_____] [_____] [_____]

[illegible]

OTHER: _____

STATUS

RESPONSE CODE

RESPONSE DATE

MAR 22 2006

33

LEWIS & HARRISON

Consultants in Government Affairs

122 C Street, N.W., Suite 740
Washington, D.C. 20001

telephone 202.393.3903
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February 28, 2006

HAND DELIVERED

Document Processing Desk (Notification)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1801 S Bell Street
Arlington, VA 22202

ATTENTION: Marshall Swindell
Product Manager, Team 33

SUBJECT: Envirox LLC
H2Orange2 117 Concentrate (EPA Reg. No. 69268-2)
Notification

Dear Mr. Marshall Swindell:


On behalf of Envirox LLC, I am submitting a label notification for their product, **H2Orange2 117 Concentrate (EPA Reg. No. 69268-2)**. This notification provides better clarity to the mixing directions for the product, by indicating the precise ounces of product to add to specific ounces of water to arrive at proper mixture (as indicated on the accepted label).

If you have any questions about the enclosed submission, please contact me by telephone at 202-393-3903 ext. 20 or by e-mail at rbrennis@lewisharrison.com.

Sincerely,



Robert S. Brennis
Agent for,
Envirox LLC.

 EPA United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other (Notification)	OPP Identifier Number 296967
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Application for Pesticide - Section I

1. Company/Product Number 69268- 2	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Envirox H2Orange2 117 Concentrate	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) Envirox LLC 1938 E. Fairchild Street Danville, IL 61832 <u>PLEASE SEND ALL CORRESPONDENCE TO</u> <u>"CONTACT POINT" LISTED BELOW</u> <input checked="" type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below


Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This notification is being made to provides better clarity to the mixing directions for the product on the label. The label now indicates the precise ounces of product to add to specific ounces of water to arrive at proper mixture (as indicated on the accepted label).

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container	<input type="checkbox"/> Plastic
					<input type="checkbox"/> Glass
					<input type="checkbox"/> Paper
					<input type="checkbox"/> Other
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container ounces of product 22 Ounces Net weight		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)		
Name: Robert S. Brennis, Lewis & Harrison 122 C St. NW, Suite 740, Washington, DC 20001	Title Agent for Envirox LLC	Telephone No. (Include Area Code) 202-393-3903 ext 20
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent for Envirox LLC	
4. Typed Name Robert S. Brennis	5. Date February 21, 2006	

Highlighted Version

H₂ORANGE₂ CONCENTRATE 117

OXIDIZING MULTI PURPOSE CLEANER, DEGREASER & SANITIZER
(NON-FOOD CONTACT SURFACES), VIRUCIDE & DEODORIZER FOR
HARD, NON-POROUS SURFACES

ACTIVE INGREDIENT	
Hydrogen peroxide	3.95%
OTHER INGREDIENTS	96.05%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Reg. No. 69268-2

EPA Est. No. 69268-IL-001

Envirox, LLC
1938 E. Fairchild St., Danville, IL 61832

NET CONTENTS:

This product is not to be used as a terminal sterilant/disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes, but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

Highlighted Version

PRECAUTIONARY STATEMENTS – HAZARDS TO HUMAN AND DOMESTIC ANIMALS

CAUTION. Causes moderate eye damage. Harmful if swallowed, absorbed through the skin, or inhaled. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling.

After product is diluted in accordance with directions for use, safety glasses or other eye protection are not required. Product, after dilution according to directions, is non-irritating.

FIRST AID

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then, continue rinsing eye. Call a poison control center or doctor for treatment advice.

If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 to 20 minutes. Call a poison control center or doctor for treatment advice.

If swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

If inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage

STORAGE AND DISPOSAL

IN CASE OF SPILL: Clean up immediately. Place leaking container in well ventilated area. To clean up spill, flush area with large quantity of water. Avoid run-off into storm sewers and ditches leading to natural waterways.

STORAGE: Do not contaminate water, food, and or feed by storage. Avoid freezing conditions. Avoid high temperatures. Do not exceed storage temperatures of 95°F Best storage temperatures are between 35°F and 85°F. Overheating in storage may result in increased degradation of product, which will decrease product effectiveness. Keep concentrate away from incompatible materials.

PESTICIDE DISPOSAL: Do not contaminate water, food or feed by disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Completely empty container. Do not reuse empty containers. If in plastic bag with original box discard in trash, sanitary landfill or by incineration, or if allowed by State and Local Authorities, by burning. If burned stay out of smoke or if in plastic bottles, triple rinse or equivalent and recycle.

Questions? Call 1-800-281-9604

Highlighted Version

DIRECTIONS FOR USE

It is violation of Federal law to use this product in a manner inconsistent with its labeling.

H₂Orange₂ Concentrate 117, when used as directed as a sanitizer, kills 99.99% of the following: *Staphylococcus aureus*, *Salmonella choleraesuis*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Streptococcus faecalis*, and *Escherichia coli*. When used as directed as a virucide, H₂Orange₂ Concentrate 117 kills the following viruses in 5 minutes or more at room temperature (20+/-1° C): Herpes simplex virus Type 2, Influenza A2/Japan, HBV (Hepatitis B Virus) and HIV-1 (Human Immunodeficiency Virus). To insure that all bacterial and viral agents are killed as stated, use 10 oz. of product concentrate per gallon (10 parts per 118 parts) of cold tap water.

CLEANING AND SANITIZING: Using the appropriate cleaning solution for the type of surface to be treated, thoroughly clean the surface, allow to air dry. If needed use additional solution. Replace mop-bucket solution daily.

TO USE AS A SANITIZER AND VIRUCIDE IN BATHROOMS: Add 10 oz. of product concentrate per gallon (10 parts per 118 parts) of cold tap water for sinks, faucets, counters, urinals, toilets (non-water covered surfaces) and all hand contact surfaces as well as walls, stalls and floors where urine and soils build up. Replace mop-bucket solution daily. Follow instructions for inanimate, hard, non-porous surfaces.

TO USE AS A SANITIZER AND VIRUCIDE ON INANIMATE, HARD, NON-POROUS SURFACES: Add 10 ounces of product concentrate per gallon (10 parts per 118 parts) of cold tap water. Apply solution liberally to pre-cleaned hard surfaces, with a spray bottle, pump up pressure sprayer with a coarse spray, cloth, sponge or mop. Allow surface to remain wet for 5 minutes, then, either allow to air dry or wipe dry to remove excess liquid. Heavily soiled surfaces should be pre-cleaned with the same solution. Replace mop-bucket solution daily.

HIV-1 and HBV: To kill HIV-1 in 5 minutes at room temperature (20-25°C) on precleaned environmental surfaces/objects previously soiled with blood/body fluids at a concentration of 1 oz / gallon (1 part of H₂Orange₂ Concentrate 117 per 127 parts of cold tap water). To kill HBV in 5 minutes at room temperature (20-25°C) on precleaned environmental surfaces/objects previously soiled with blood/body fluids at a concentration of 10 oz / gallon (10 parts per 118 parts). For use in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surface/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type I (HIV-1 Associated with AIDS) or HBV (Hepatitis B Virus).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HBV (HEPATITIS B VIRUS) AND HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

Personal Protection: Wear appropriate barrier protection such as latex gloves, gowns, masks or eye coverings.

Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of diluted product using the Heavy or Super Duty Cleaning Solution.

Contact time: While the HIV-1 virus is inactivated in 5 minutes, at use concentration of 1 oz / gallon, with both organic load and when diluted in hard water (up to 400 ppm hardness), use the recommended contact time for sanitization and virucidal activity as given on this label. For HBV, use concentration of 10 oz/gallon (10 parts per 118 parts) and leave surfaces wet for 5 minutes.

Infectious Materials Disposal: Cleaning materials that may contain blood and other body fluids should be disposed of by autoclaving or as directed by the facility safety officer.

Highlighted Version

DEODORIZING

For general deodorizing, use 2 parts H₂Orange₂ Concentrate 117 per 126 parts of cold tap water (2 oz / gallon). Apply to hard, non-porous surfaces to eliminate generally offensive odors. For effective, high level, deodorizing, use 10 parts H₂Orange₂ Concentrate 117 to 118 (10 oz / gallon) parts of cold tap water. Apply to hard, non-porous surface thoroughly to eliminate odors due to spillage from post-colostomy, post-ileostomy dressing and bag changes, and other spills such as urine or fecal matter; smoke or soot deposits, industrial plant processes, mildew and mold stains, and surfaces in musty closets.

CLEANING SOLUTION DILUTIONS & APPLICATIONS

LIGHT DUTY (1 Oz / gal) GREEN (bottle or label)

Streak free window, mirror and stainless steel cleaning
General floor cleaner for mopping & auto scrubbers
Bonnet cleaning solution for carpets
Light wipe down cleaner

GENERAL PURPOSE (2 Oz / gal) BLUE (bottle or label)

General wipe down cleaner
Mopping solution for Bathroom and Kitchen floors
General carpet spot remover

HEAVY DUTY (10 Oz / gal) RED (bottle or label)

Bathroom, shower room, tile & grout cleaner
Urine and garbage odor eliminator
Pre-spray for carpet extraction
General degreaser
Heavy soil wipe down cleaner
Heavy carpet spot remover
Cleans Mold & mildew stains

SUPER DUTY (24-48 Oz / gal) PURPLE (bottle or label)

Renovation of tile & grout surfaces
Difficult urine & garbage odor destruction
Scuff marks and stubborn stains
Cleans heavy mold & mildew stains

OPTIONAL MARKETING STATEMENTS: (one or more or none of the following may appear)

Registered for control of [Hepatitis B Virus]/[HBV]
Registered to kill [Hepatitis B Virus]/[HBV]

Notif: Clarification of statement 02/28/2006

Explore Registration

Reg Number: 69268-2 Reg Type: Product Registration - Section 3 Status: Conditionally Registered (10-Sep-1)

Name: H2ORANGE2 CONCENTRATE 11.7

<View Registration Details>

(New Receipts)

S	Submission Type	OPP Rec'd Date	Resubmission	Description
763370	6A2 Data	22-Aug-2005	<input type="radio"/> Yes <input checked="" type="radio"/> No	efficacy report

- Decisions...
- D: Pending; 365791, 69268-2, 332, NOTIFICATION
- D: Closed; 357972, 69268-2, 332, NOTIFICATION
- D: Closed; 356273, 69268-2, 332, NOTIFICATION
- D: Closed; 351212, 69268-2, 332, NOTIFICATION
- D: Closed; 345946, 69268-2, A57, AMENDMENT
- D: Closed; 205867, 69268-2, 332, NOTIFICATION
- D: Closed; 205866, 69268-2, 332, NOTIFICATION
- D: Closed; 205865, 69268-2, 302, LABEL REVISION
- D: Closed; 205864, 69268-2, 332, NOTIFICATION
- D: Closed; 205863, 69268-2, 307, DATA REQUIREMENT
- D: Closed; 205862, 69268-2, 302, LABEL REVISION
- D: Pending; 205861, 69268-2, 332, NOTIFICATION
- D: Closed; 205860, 69268-2, 322, DATA REQUIREMENT
- D: Closed; 205859, 69268-2, 362, FORMULA CHANGE
- D: Pending; 205858, 69268-2, 172, NEW REGISTRATION

S: 791417 Reg #: 69268-2

Submission Type: Notification

Resubmission: ☐ Yes ☒ No

Decision #: 365791, 332, NOTIFICATION

Submitter Company: ENVIROX LLC

Application Date: 28-Feb-2006

OPP Received Date: 06-Mar-2006 Date Sent to Risk manager: 08-Mar-2006

Studies Included? ☐ Yes ☒ No Fast Track? ☐ Yes ☒ No

Form A Signed? ☐ Yes ☐ No ☒ None Date:

Form B Signed? ☐ Yes ☐ No ☒ None Date:

Reviewer: Leavy, Karen

Received DT: 08-Mar-2006 Editable Due DT:

Submission Due DT: 05-Apr-2006 Response DT: 05-Mar-2006

Priority Weight: Priority Points:

Comments: minor label change

~~Karen~~

~~Due 4/5/06~~

AI

Make code sheet

Mail & Date 3/22/06 3/14/06

Closed in oppen